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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,854	03/07/2002	Felix Kratz	25048/20	6344

7590 07/06/2007
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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07/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/009,854

Applicant(s)

KRATZ, FELIX

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-30, 32-34 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 21, 25, 38 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 22-24, 26-30, 32-34, 36, 37, 39-41 and 43-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 14, 2007 has been entered.

2. Applicant has mis-numbered the new claims in the listing of claims submitted June 14, 2007, and has omitted claim 35, submitted with the amendment after final rejection filed January 19, 2007 but not entered, from the listing of claims. Note that claims retain their claim numbers whether entered or not (see 37 CFR 1.126), and that claim 35, submitted with the amendment after final rejection filed January 19, 2007 but not entered, should be listed in the listing of claims with the status identifier “(not entered)” (see 37 CFR 1.121(c)). Accordingly, the new claims contained in the amendment filed June 14, 2007, which Applicant has numbered 35-49 have been re-numbered 36-50, respectively. See 37 CFR 1.126. Any future reference to the claims will use the re-numbered claim numbers. In the response to this Office action, Applicant must submit a complete listing of the claims using the re-numbered claim numbers, including claim 35 (not entered) and claims 36-50. The dependency of claims 20, 22, 23, 25-28, 32, 33, and 37-50 will have to be corrected to show the re-numbered claim numbers.

3. Applicant's election of the species in the reply filed on November 13, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 21, 25, 38, and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 13, 2003.

4. The disclosure is objected to because of the following informalities: In amended paragraph [0073], second-to-last line, "Iic" should be changed to "Ile". Compare Figure 2B. The SEQ ID NO inserted into paragraph [0073] does not correspond to the amino acid sequence shown in Figure 2. It would be acceptable to amend paragraph [0073] to read, e.g., "(residues 1-4 of SEQ ID No. 9)". In amended paragraph [0055], second-to-last line, the SEQ ID NO does not completely describe all of the amino acid sequences encompassed by the formula. Further, it is noted that SEQ ID NOS:10-27, listed in the Sequence Listing filed February 6, 2006, are not used in the specification as currently amended. It is suggested that in amended paragraph [0055], second-to-last line, the SEQ ID NO could be changed to "SEQ ID Nos. 8 and 10-27". Applicant is requested to re-supply by appropriate amendment the top line of page 25 of the specification. The current scanned image is partially obscured due to hole punching in the original source. Appropriate correction is required.

Applicant did not re-supply the top line of page 25 by appropriate amendment, but rather merely provided a portion of the appropriate paragraph without an amendment instruction. Current amendment rules require submission of entire paragraphs.

5. Applicant is advised that should claims 20-30 and 32-34 be found allowable, claims 37-50 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the

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same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 37-50 are identical in scope with claims 20-30 and 32-34, respectively.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 20, 22-24, 26-30, 32-34, 36, 37, 39-41, and 43-50 are rejected under 35 U.S.C. 102(a) as being anticipated by the Kratz et al article (J. Med. Chem., Vol. 43, pages 1253-1256). The Kratz et al article teaches treating albumin with dithiothreitol so that approximately one mole sulfhydryl group (from Cys34) per molecule of albumin is obtained. The treated albumin is then reacted with the doxorubicin derivative of Figure 1. The doxorubicin derivative of the Kratz et al article has the same structure as Applicants' elected species. The pure conjugate has a drug:albumin ratio of approximately 0.9:1. See, e.g., page 1254, column 1, second full paragraph. With respect to instant claim 32, while the Kratz et al article does not intend to administer the pure conjugate in vivo to animals with cancer (instead, the Kratz et al article intends to administer the doxorubicin derivative of Figure 1 in vivo, where it reacts with endogenous albumin), an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claims 33 and 34, the pure conjugate of the Kratz et al article is deemed to anticipate the instant kit claims, whose only recited element is the carrier-drug conjugate.

8. Claims 33, 34, 49 and 50 are rejected under 35 U.S.C. 103(a) as being obvious over the Kratz et al article (J. Med. Chem., Vol. 43, pages 1253-1256). Application of the Kratz et al article is the same as in the above rejection of claims 20, 22-24, 26-30, 32-34, 36, 37, 39-41, and

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43-50. To the extent that the Kratz et al article might not teach its conjugate in kit form, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to package the conjugate of the Kratz et al article in kit form because kits are routinely used in the pharmaceutical and chemical assay arts for purposes of storage, transportation, measurement, and administration.

9. Applicant's arguments filed June 14, 2007 have been fully considered but they are not persuasive.

The rejections based upon the WO Patent Application 98/10794 are withdrawn in view of the amendments to the claims.

The prior art rejections over the Kratz et al article (J. Med. Chem., Vol. 43, pages 1253-1256) are maintained. Applicant has not submitted a translation of the foreign priority document, DE 19926475.9, and therefore Applicant has not perfected his claim for priority under 35 U.S.C. 119(a)-(d).

10. Smith (U.S. Patent No. 7,105,160 - see, e.g., claims 1-2), Bridon et al (U.S. Patent No. 7,090,851 - see, e.g., claim 1), and Ezrin et al (U.S. Patent No. 6,706,892 - see, e.g., column 94, lines 4-32) disclose conjugates in which various agents are conjugated to the Cys34 residue of albumin. However, these references do not teach or suggest that some point in the linkage between the agent and the albumin should be cleavable, as is required by the instant claims.

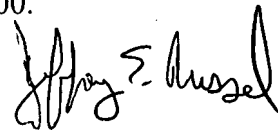
The Yasuzawa et al article (Bioconjugate Chemistry, Vol. 8, pages 391-399) is cited as art of interest, but is not deemed to teach or suggest Applicant's claimed invention. The Yasuzawa et al article teaches a conjugate in which mitomycin C will be linked via a 7-N-(2-mercaptoethyl) group to the Cys-34 residue of human serum albumin. See, e.g., the Abstract and

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Figures 2 and 8. However, this conjugate will be cleavable at the disulfide group which occurs between the albumin and the thiol binding group, which is not one of the cleavage locations recited in instant claim 36, part (iv).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Jeffrey E. Russel". The signature is stylized with a large initial "J" and a cursive "E".

Jeffrey E. Russel

Primary Patent Examiner

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JRussel
June 25, 2007